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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/087,667

02/28/2002

A. John Bramley

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7908

24280

7590

04/25/2003

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EXAMINER

WOITACH, JOSEPH T

ART UNIT

PAPER NUMBER

1632

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Please find below and/or attached an Office communication concerning this application or proceeding.

File

# Office Action Summary

Application No.  
10/087,667

Applicant(s)  
Bramley et al.

Examiner  
Joseph Weitach

Art Unit  
1632



-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on Feb 28, 2002
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11; 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 27-64 is/are pending in the application.
- 4a) Of the above, claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☐ Claim(s) \_\_\_\_\_ is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claims 27-64 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.  
If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).  
a) ☐ All b) ☐ Some\* c) ☐ None of:  
1. ☐ Certified copies of the priority documents have been received.  
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_  
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).  
\*See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).  
a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892) 4) ☐ Interview Summary (PTO-413) Paper No(s). \_\_\_\_\_
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948) 5) ☐ Notice of Informal Patent Application (PTO-152)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s). \_\_\_\_\_ 6) ☐ Other:

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### **DETAILED ACTION**

This application filed February 28, 2002, is a continuation-in-part of application 09.337,079, filed June 21, 1999, now abandoned, which claims benefit to provisional application 60/090,175, filed June 22, 1998.

Applicants preliminary amendment filed February 28, 2002, paper number 6, has been received and entered. Claims 1-26 have been canceled. Claims 27-36 have been amended. Claims 37-64 have been added.

It is noted that claim 51 recites that "the lysostaphin polypeptide is secreted" however there is no recitation of "lysostaphin" in claim 51 or the independent claim 50. For the sake of compact prosecution the claim is being interpreted as a non-mammalian anti-microbial protein as supported in claim 50.

Claims 27-64 are pending.

### ***Election/Restriction***

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 27-31, 37-40, 61-64, drawn to non-human transgenic mammal comprising an altered lysostaphin gene, classified in class 800, subclass 14.
- II. Claims 32-36, 37-49, drawn to non-human transgenic mammal comprising an altered non-mammalian anti-microbial gene, classified in class 800, subclass 14.

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- III. Claims 50-60, drawn to non-human transgenic mammal comprising a transgene wherein said transgene comprises a polynucleotide sequence that encodes an altered non-mammalian anti-microbial gene wherein said alteration is a disruption in at least one glycosylation site in the encoded protein, in operably linkage to a tissue specific promoter, classified in class 800, subclass 14.

Claims 37-40 are generic to groups I and II, and will be examined to the extent they encompass to the elected invention.

The inventions are distinct, each from the other because of the following reasons:

Inventions I-III are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions are directed to different products. In each case each of the inventions are directed to different transgenic non-human mammals comprising different transgenes. The different transgenes represent materially different starting materials required to generate the transgenic mammal, and provide for different transgenic mammals materially different at a genetic level and phenotypically different if the transgene is produced and functional in said non-human mammal.

Because these inventions are distinct for the reasons given above and the search required for Group I is not required and different from that for Groups II-III, restriction for examination purposes as indicated is proper.

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**In addition**, if group III is elected an additional election of species is required. This application contains claims directed to the following patentably distinct species of the claimed invention: claims 52-60 are recite specific and structurally different anti-microbial genes encoding the heterologous peptide/protein. Specifically, a single species selected from the group of : (1) an anti-viral peptide/protein, (2) a microbial peptide/protein, (3) a prokaryotic peptide/protein, (4) a bacterial peptide/protein, (5) a nisin, (6) a muramindase, (7) a glucoasminidase, (8) a endopeptidase, (9) a colicin, (10) an anti-staphylococcal, (11)  $\beta$ -lytic protease, (12) lysostaphin, (13)  $\alpha$ -lytic protease, (14) lyt-M, (15) at1ALE-1 and (15) zooA, must be elected. Only one specific anti-microbial gene listed above must be indicated if group III is elected.

Applicant is required under 35 U.S.C. 121 to elect a single disclosed species for prosecution on the merits to which the claims shall be restricted if no generic claim is finally held to be allowable. Currently, claims 50 and 51 are generic.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after

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the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Joseph Woitach whose telephone number is (703)305-3732.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Deborah Reynolds, can be reached at (703)305-4051.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group analyst Dianiece Jacobs whose telephone number is (703) 308-2141.

Papers related to this application may be submitted by facsimile transmission. Papers should be faxed via the PTO Fax Center located in Crystal Mall 1. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The CM1 Fax Center numbers are (703)308-4242 and (703)305-3014.

Joseph T. Voitach

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AU 1632